

**Baxter**

Surgical Group

Baxter Healthcare Corporation  
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MAR 17 1997

**K964029****SUMMARY OF SAFETY AND EFFECTIVENESS**  
**Appendix E**

**Manufacturer:** Baxter Healthcare Corporation  
Surgical Group  
Thermal  
808 Highway 24 West  
Moberly, Missouri 65270

**Regulatory Affairs Contact:** Maryalice Smith  
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**Date Summary Prepared:** September 20, 1996

**Product Trade Name:** Baxter Emergency Relief™ Kit System

**Classification:** Class I [21CFR not listed]  
Product Code 79LRR

**Predicate Device:** Each component within the Emergency Relief System is a finished good with an established regulatory path when applicable. The devices which fall within this category include the following:

1.	Gauze Dressing	Class I Exempt 21CFR 878.4450
2.	Oval Eye Pad	Class I Exempt 21CFR 878.4440
3.	Vinyl Gloves	Class I 21CFR 880.6250 Baxter K952786 Bulk Non-Sterile
4.	Adhesive Tape	Class I Exempt 21CFR 880.5240

## Predicate Device:

- |     |                                      |  |
|-----|--------------------------------------|--|
| 5.  | Scissors                             | Class I Exempt<br>21CFR 878.4800   |
| 6.  | Sterile Saline<br>For Eye Irrigation | Over-The-Counter<br>21CFR 349.20   |
| 7.  | Metal Extremity<br>Splint            | Class I Exempt<br>21CFR 378.3910   |
| 8.  | Cold Pack                            | Preamendment<br>Baxter Thermal   |
| 9.  | Bandage Strips                       | Class I Exempt<br>21CFR 880.5240   |
| 10. | Topical Antiseptic<br>Ointment       | Over-The-Counter<br>21CFR 333.110(a)   |
| 11. | Alcohol Swab                         | Over-The-Counter<br>21CFR<br>333.460(b)(2)<br>Tenative Final<br>Monograph for<br>Health Care<br>Antiseptic Drug<br>Products; Proposed<br>Rule. |

## Description:

The Baxter Emergency Relief™ System is designed as one large unit which houses various first aid kits. Each mini kit contains various individual components traditionally used for first aid treatment. Each individual component is a finished good with an established regulatory path where applicable. All components are purchased as finished goods and packaged in the appropriate mini kit, including direction for use inserts. All direction for use inserts correspond to the instruction manual accompanying the system.

## Intended Use:

The Baxter Emergency Relief™ System consists of color-coded mini first aid kits. Each kit is intended to be used as a basic first aid treatment for various emergency situations, while seeking further professional medical assistance.

**Substantial Equivalence:**

The Emergency Relief™ Kit System  
substantial equivalency is established by each  
device component contained within the mini  
kits in that:

- intended use is the same

**Summary of Testing:**

Testing of the system was deemed not  
applicable as all regulated devices has an  
established regulatory path and is obtained in  
finished good form